**OHRP Determination of Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (October 8, 2020)**

To ensure that institutions conducting cooperative research are able to take advantage of the most appropriate IRB review structure, the Office for Human Research Protections (OHRP) in the Office of the Assistant Secretary for Health of the Department of Health and Human Services has determined that, for studies that are conducted or supported by HHS and subject to the 2018 Requirements, and for purposes of 45 CFR 46.114(b) (2)(ii), an exception to the requirement to use a single IRB is appropriate for the following category:

Cooperative research:

1. that is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>;
2. where reliance on a single IRB would not be practical; and
3. for which the HHS division supporting or conducting the research approves of the use of this exception.

This exception applies for the duration of the HHS-conducted or supported research.

OHRP has made this exception determination due to concerns regarding the application of the single IRB requirement to cooperative research subject to the 2018 Requirements when this research is initially reviewed or ongoing during the COVID-19 public health emergency. The COVID-19 public health emergency has created unprecedented burdens and disruption to the research enterprise, while at the same time requiring urgent research responses that necessitate flexible approaches to oversight in order to provide vital information and to allow other research to continue where possible. This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak.

The exception includes some scenarios for which OHRP anticipates it may not be practical to rely on use of a single IRB for multi-site, cooperative research trials during the ongoing COVID-19 pandemic. This exception determination can be accessed on OHRP website at: <https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/october-2020-exception-determination/index.html>.

OHRP’s November 2019 Determination of Exception and related background information can be accessed at: <https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html>.